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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,925	01/03/2005	Tasuku Honjo	Q85588	9146

65565 7590 01/19/2007  
SUGHRUE-265550  
2100 PENNSYLVANIA AVE. NW  
WASHINGTON, DC 20037-3213

EXAMINER
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OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,925	<b>Applicant(s)</b> HONJO ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 and 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6, 12-17 and 27-32 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

**1. Claims 1 – 32 are pending.**

2. Claims 7 – 11 and 18 – 22 are improper because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n) and 37 CFR § 1.75(c). Therefore, these claims have been withdrawn from consideration.

If these claims are amended to comply with 37 CFR § 1.75(c), the amended claims may be rejoined with the appropriate invention Group as set forth below, or subject to an additional restriction requirement, as appropriate.

3. It is noted that claims 23 – 26 are directed to the "use" of a compound. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore, claims 23 – 26 have been withdrawn from consideration as being drawn to non-statutory subject matter. If these claims are amended to recite statutory subject matter, the amended claims may be rejoined with the appropriate invention Group as set forth below, or subject to an additional restriction requirement, as appropriate.

**4. Claims 1 – 6, 12 – 17, and 27 – 32 are under consideration in the instant application.**

***Restriction Requirement***

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1 – 6, drawn to an immunopotentiative composition comprising an immunosuppressive signal inhibitor of PD-1, PD-L1, or PD-L2.

II. Claims 12 – 14 and 16, drawn to a method for treatment of cancer, comprising administering an immunosuppressive signal inhibitor of PD-1, PD-L1, or PD-L2.

III. Claims 12, 15, and 17, drawn to a method for treatment of an infection, comprising administering an immunosuppressive signal inhibitor of PD-1, PD-L1, or PD-L2.

IV. Claim 27, drawn to a carcinoma cell line, transformed to express PD-L1 or PD-L2.

V. Claims 28 – 30, drawn to a method of screening, comprising contacting a test substance with a cell expressing PD-L1 or PD-L2.

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VI. Claim 31, drawn to a mammal prepared by transplanting a carcinoma cell expressing PD-L1 or PD-L2.

VII. Claim 32, drawn to a method of screening for a substance for treatment of cancer, comprising administering a test substance to a mammal which comprises a carcinoma cell expressing PD-L1 or PD-L2.

6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

7. The inventions listed as Groups I – VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I – VI are deemed to have no special technical feature that defined the contribution over the prior art of Freeman et al. (US Pat. Pub. No. 2002/0164600; see entire document).

Freeman et al. teach antagonist antibodies to PD-L2 (e.g. paragraph 0331), i.e. antibodies which inhibit the activity of PD-L2. Since PD-L2 provides an immunosuppressive signal, the inhibitory antibody of Freeman et al. inherently inhibits the immunosuppressive signal of PD-L2. Freeman et al. also teach that compositions comprising said antibody can be used for treating cancer (e.g. paragraph 0367). Therefore, the teachings of Freeman et al. anticipate the instant claimed inventions, which thus do not contribute a special technical feature over the prior art.

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Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and so lack unity of invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive, flowing style with a large initial "I".

January 12, 2007